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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/460,324	12/10/1999	KENNETH J. KASHA	411044.9002	2350

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EXAMINER	
GRUNBERG, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1661	9

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/460,324	Kenneth J. Kasha et al.
Examiner	**Art Unit**
Anne Marie Grunberg	1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 4, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) *23, 24, and 28-30* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *1-22 and 25-27* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3, 6*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

The reference from Hunter, submitted with paper #3 on 6 March 2000 was considered but was lined through on the IDS, as the reference is incomplete. It is missing pages 39-44 of Chapter 2. The reference has not been considered at this time as a result. However, if Applicant sends in the missing pages with the next correspondence, the Examiner will consider the reference at that time.

Election/Restrictions

1. Applicants' election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the subject matter of the two groups is highly interrelated and that any search would inevitably include the same subject matter that is searched for the claims of Group I, especially since the claims in Group II are all dependent claims.

These arguments have been carefully considered and are not found persuasive for the following reasons. The plant embryo, plant, transgenic microspore, transgenic embryo, and transgenic plant, are products can be made by any method, for example one that does not utilize

arabinogalactin in the medium. In such a case it would be impossible to tell the product made by one method as opposed to the same product made by a materially different method. As a result, the searches are not coextensive.

The requirement is therefore still deemed proper and is made FINAL.

Applicants are reminded to cancel claims drawn to the non-elected inventions in the next correspondence with the Office.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 17, and 18, and dependent claims 2-16, 19-21, and 25-27, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18, and dependent claims 2-16, 19-21, and 25-27 are vague and indefinite due to the recitation "a substantial portion". It is unclear what constitutes a "substantial" portion, nor is it defined in the specification. Is 10% a "substantial" portion? Or 90%? Applicant should clarify this without introducing new matter.

Claim 17 is vague and indefinite because there is no antecedent basis in the recitation of "microspore". Step (a) of claim 1 refers to a "microspore-containing plant segment" rather than a "microspore". This rejection may be obviated by inserting --containing plant segment-- after "microspore".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (In Vitro Cell Dev.)

Claim 18 is drawn to a method of plant regeneration wherein a microspore-containing plant segment from a donor plant is incubated under pre-treatment conditions to maintain a substantial portion of microspores at a uninucleate cell cycle G1 phase. The microspores are then isolated from the segment and incubated on an induction medium comprising an auxin to produce differentiated embryos. Plants are then regenerated from these embryos.

Hu et al teach a method of plant regeneration wherein a microspore-containing plant segment from a donor plant is incubated under pre-treatment conditions to maintain a substantial

portion of microspores at a uninucleate cell cycle G1 phase (page 79, column 2, 1st paragraph under Materials and Methods; page 80, column 1, 1st paragraph after *"Pretreatment experiments"*). Although Hu et al do not expressly state that a substantial portion of microspores are at a uninucleate cell cycle G1 phase, the pretreatment processing ensures that this is the case. The anthers were collected from the central two thirds of a spike and they were put into mannitol (bottom of page 79 and top of page 80). The microspores are then isolated from the segment (page 80, column 1, first paragraph under "*Microspore isolation methods*") and incubated on an induction medium comprising an auxin (page 80, column 1, paragraph after "*Phenylacetic acid evaluation*") to produce differentiated embryos (page 80, first column, paragraph after "*Plant regeneration*"). Plants are then regenerated from these embryos (page 80, first column, first and second paragraph after "*Plant regeneration*").

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12, are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al. in view of Kreuger et al (EP 0 455 597).

Claims 1-12, are drawn to a method of producing an embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion (50-100%) of microspores are maintained at a uninucleate cell cycle G1 phase. Microspores are then isolated from the segment and incubated in an induction medium comprising arabinogalactan to induce embryogenesis and thereby produce embryos. The donor plant may be a cereal, such as wheat or barley. The arabinogalactan may be present in the induction medium in an amount ranging from 1 mg/liter - 100 mg/liter, or from 10 mg/liter - 25 mg/liter and may be present for about two weeks. The pre-treatment conditions may include a temperature between 3-10°C for 3-10 days wherein incubation occurs in an aqueous solution containing 0.2-1.0 mol/liter sugar alcohol such as mannitol. The incubation may also occur in

the aqueous medium for 7 to 28 days at a temperature of 3-10°C. The induction treatment may be from 3-14 days and may contain an auxin.

Genovesi et al teach a method of producing an embryo wherein a microspore-containing plant segment is harvested from a donor plant and incubated under pre-treatment conditions wherein a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase (column 4, lines 20-24, 66-68; column 5, lines 5-8, for example). The microspores are isolated from the segment and incubated in an induction medium to induce embryogenesis (column 4, lines 34-35; column 6, lines 52-55; for example), thereby producing embryos (column 8, lines 6-9, 24-25, 43, 52; for example). Genovesi et al teach the method wherein the donor plant is a cereal wheat plant such as barley (column 4, line 3). Although Genovesi et al do not specifically teach that a substantial portion of microspores at a uninucleate cell cycle G1 phase comprises from 50-100%, this would appear to be the case because of the stress treatments, ie mannitol and cold treatments (column 4, lines 20-24; column 19, lines 14-24, for example). The pre-treatment conditions comprise a temperature of from about 3-10°C for 3 to 10 days and incubation in an aqueous solution having from about 0.2 mol/liter to about 1.0 mol/liter sugar alcohol (column 5, lines 9-14, 33-35, 53-64, for example). Mannitol is described at column 5, lines 55-62, for example). The pre-treatment conditions include an aqueous solution (column 24, lines 20-32, for example) and as such, the incubation occurred in water containing other items as well. Since claim 10 is not limited to only water, the prior art reads on it as described above. Tassels and/or

anthers are described in column 4, line 21; and column 28, line 40, for example. Genovesi teach microspores incubated in induction medium for about twelve days (column 8, lines 35-38).

Genovesi et al do not teach arabinogalactan to induce embryogenesis.

Kreuger et al teach arabinogalactan to induce embryogenesis (column 3, lines 14-18). They teach a range of 0.01 to 100 mg/liter at column 3, line 12. However, they teach at lines 14-18 that 0.1-20 mg/liter or 1-10 mg/liter are preferred for embryogenesis induction. At column 6, line 22, they teach 18 days of culture in arabinogalactan containing medium.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing an embryo as taught by Genovesi et al and to modify it to include the addition of arabinogalactan as taught by Kreuger et al given the dramatic stimulation in embryogenic growth with the use of arabinogalactan as reported by Kreuger et al. Kreuger et al state in column 2, lines 30-32, that the method (of using arabinogalactan in tissue culture processes) is "generally applicable, including for anther and microspore cultures."

8. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al in view of Hu et al. (Plant Cell Reports)

Claims 18-21 are drawn to a method of plant regeneration from microspores wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell

cycle G1 phase. Microspores are then isolated from the segment and incubated in an induction medium comprising an auxin to induce the production of embryos. The embryos are then incubated in a differentiation medium to produce differentiated embryos which are the regenerated into plants. The embryos may be placed on a support such as filter paper. The microspores may be isolated by blending or vortexing the segment in an aqueous solution of about 0.2-1.0 mol/liter sugar alcohol.

Genovesi et al teach a method of plant regeneration from microspores wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase (column 4, lines 16-24, for example). Microspores are then isolated from the segment and incubated in an induction medium (column 4, lines 31-33, for example) to induce the production of embryos (column 4, lines 34-35, for example). The embryos are then incubated in a differentiation medium to produce differentiated embryos which are the regenerated into plants (column 4, lines 35-41; column 8, lines 17-29, for example). The embryos may be placed on a support (column 7, lines 14-15, 24-31) such as filter paper (column 7, lines 14-15). The microspores may be isolated by blending or vortexing the segment (column 6, lines 15-18) in an aqueous solution.

Genovesi et al do not teach an induction medium comprising an auxin. Nor do they teach an isolation medium comprising about 0.2-1.0 mol/liter sugar alcohol.

Hu et al teach an induction medium comprising an auxin (page 521, Table 1, for example). Hu et al also teach an isolation medium comprising 0.4 M mannitol (page 521, column 1, paragraph under "Pretreatment of anthers and isolation of microspores").

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of plant regeneration from microspores as taught by Genovesi et al and to modify it to include mannitol in the isolation as taught by Hu et al, given that it would be beneficial to keep the microspores arrested at the uninucleate cell cycle until they were ready to be incubated. Genovesi et al, kept the microspores in mannitol until isolation and if one was to use the microspores immediately, then it wouldn't matter if the microspores were removed from the mannitol. However, it would have been expedient to keep them in mannitol until the time they were to be incubated. It would have been obvious to use an auxin in the induction medium given the benefits of improving microspore division and embryogenesis in wheat as described by Hu et al (page 520, column 2, second paragraph, for example).

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being anticipated by Kreuger et al (EP 0 455 597) in view of Genovesi et al or Hu et al. (Plant Cell Reports)

Claim 22 is drawn to a method for microspore culture of a cereal plant wherein a microspore-containing plant segment is incubated in a medium comprising arabinogalactan in a quantity of from about 1 mg/liter to about 100 mg/liter to create embryos that are regenerated into cereal plants.

Kreuger et al teach a method for microspore culture of any kind of plant (column 2, lines 30-32) wherein a microspore-containing plant segment is incubated in a medium comprising arabinogalactan in a quantity of from about 0.01 mg/liter to about 100 mg/liter (column 3, lines 10-22) to create embryos. Kreuger et al teach that plant cells have the potential to regenerate into plants column 1, lines 1-20.

Kreuger et al do not teach a cereal plant specifically, nor do they teach specific regeneration into cereal plants.

Genovesi et al teach microspore culture of maize cereal plants and their regeneration into cereal plants (claim 1, for example).

Hu et al teach microspore culture of wheat cereal plants and their regeneration into cereal plants (page 521).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of microspore culture as taught by Kreuger et al and to modify it to include cereal plants as taught by Genovesi et al or Hu et al, given that cereals are the most important agronomic crop and both Hu et al and Genovesi et al teach improved functional methods of cereal microspore culture and subsequent cereal regeneration.

10. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al and Kreuger et al in view of Chang et al

Claims 25-27 are drawn to a method of introducing a gene of interest into a microspore wherein a genetic construct with a gene of interest is introduced into the microspore obtained as in claim 1. Particle bombardment may be used or *Agrobacterium* mediated transformation.

Genovesi et al in view of Kreuger et al, as they read on claim 1 have been discussed previously.

Genovesi et al and Kreuger et al do not teach genetic transformation.

Chang et al teach genetic transformation using particle bombardment of microspores (column 2, lines 12-19, for example). Official notice is given that *Agrobacterium* mediated transformation would be obvious to use on dicots susceptible to infection as alluded to by Chang et al in column 1, lines 30-33.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of microspore culture as taught by Genovesi et al and Kreuger et al and to include transformation procedures as taught by Chang et al or as is well-known in the art, given that transformation of plants is desirable in order to implant disease resistance, for example, into a cultivar. Genovesi et al teach also teach transformation of microspores in one embodiment (column 5, lines 47-52).

(Plant Cell Reports)

11. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al in view of Kreuger et al.

Claims 13-17 are drawn to a method of producing an embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase. Microspores are then isolated from the segment and incubated in an induction medium comprising arabinogalactan to induce embryogenesis and thereby produce embryos. The induction medium comprises an auxin and may be phenylacetic acid. Glutamine, from about 500 to about 1000 mg/L, may be present in the induction medium. The induction medium may also comprise ovary co-culture and the microspore(s) may be obtained from wheat.

Hu et al teach method of producing a wheat embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase (page 521, column 1, lines 8-13, for example). Microspores are then isolated from the segment (page 521, column 1, lines 13-15) and incubated in an induction medium to induce embryogenesis and thereby produce embryos (page 521, column 1, paragraph under "Culture media"). The induction medium comprises an auxin and may be phenylacetic acid (page 521, Table 1). Glutamine, from about 500 to about 1000 mg/L, may be present in the induction medium (page 521, Table 1). The induction medium may also comprise ovary co-culture (page 521, column 2, paragraph under "Ovary co-culture).

Hu et al do not teach arabinogalactan in the induction medium.

Kreuger et al teach arabinogalactan to induce embryogenesis (column 3, lines 14-18).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing an embryo as taught by Hu et al and to modify it to include the addition of arabinogalactan as taught by Kreuger et al given the dramatic stimulation in embryogenic growth with the use of arabinogalactan as reported by Kreuger et al. Kreuger et al state in column 2, lines 30-32, that the method (of using arabinogalactan in tissue culture processes) is "generally applicable, including for anther and microspore cultures."

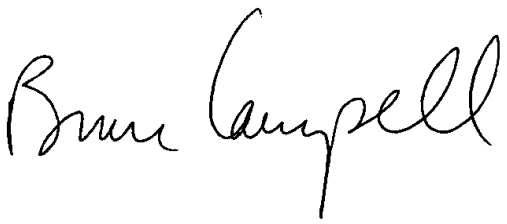
Summary

No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grünberg whose telephone number is (703) 305-0805. The examiner can normally be reached from Monday through Thursday from 7:30 until 5:00, and every other Friday from 7:30 until 4:00.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (703) 308-4205. The fax number for the unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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